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2	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
_	10/044,486	01/11/2002	Roger Y. Tsien	REGEN1510-1	9885
	7590 04/29/2003				
	Gray Cary Ware & Freidenrich LLP			EXAMINER	INER
	4365 Executive San Diego, CA	Drive, Suite 1100 92121-2133		LILLING, HERBERT J	
				ART UNIT	PAPER NUMBER
				1651	
				DATE MAILED: 04/20/2003	•

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
Office Action Summary	10/044,486	TSIEN ET AL					
Office Action Summary	Examiner	Art Unit					
The MAIL INC DATE of this communication and	HERBERT J LILLING	1651					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1) Responsive to communication(s) filed on	·						
_ =	is action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) 1-16 is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) 1-16 are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
,	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:							
, , ,	1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No							
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
4) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li></ol>	5) Notice	w Summary (PTO-413) Paper No(s) of Informal Patent Application (PTO-152)					
J.S. Patent and Trademark Office							

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1. Claims 1-16 are pending in this application which claims benefit to Provisional Application No. 60/261,313 filed 01/12/2001.

## Election/Restrictions

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-4, drawn to compounds as representative by general formula I, classified in numerous classes under 540+, as well as numerous subclasses depending upon the substituents A, R and Z.
  - II. Claims 5-13, drawn to methods of detecting the presence of Betalactamase activity, classified in class 435, subclass 7.4.
  - III. Claims 14-16, drawn to a method for determining whether a compound of Formula I is a substrate for a Beta-lactamase enzyme by exciting at the wavelength of the compound when cleaved and measuring the fluorescence, classified in class 435, subclass 173.2.
- Inventions I and II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product e.g., fluorescence labeling of various other enzymes.

Inventions II does not require the specifics of Invention III.

- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for the other invention, thusly the restriction for examination purposes as indicated is proper.
- 5. This application contains claims directed to the following patentably distinct species of the claimed invention:

Whereby the general formula I contains:

- a. R is selected from
  - i. benzyl,
  - ii. 2-thienylmethyl,
  - iii. cyanomethyl;
- b. R' is selected from
  - i. H,
  - ii. salts or metals, ammonium cations,
  - ester groups ? [please specify],

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- iv. acylthiomethyl,
- v.  $--CHR2OCO(CH_2)_n CH_3$ ,  $--CHR2OCO(CH_3)_3$ ,
- vi. phenyl,
- vii. methylsulphinylmethyl,
- viii. beta morpholineoethyl,
- ix. dialklylaminoethyl,
- x. dialkylaminocarbonyloxymethyl;

THERE IS NO R2 IN THE FORMULA.....? PLEASE INDICATE WHERE IN THE FORMULA I IS R2.

- c. Whereby A is selected from
  - i. S,
  - ii. O,
  - iii. SO,
  - iv. SO<sub>2</sub>
  - v. CH<sub>2;</sub>
- d. Whereby Z is a fluorescent moiety selected from
  - i. II,
  - ii. III,
  - iii. IV,
  - iv. V,
  - v. VI,

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vi. VII,

vii. VIII,

viii. VIII,

ix. IX,

x. X,

xi. XI;

and

e. Whereby the linker is selected from the group as noted by one of the groups noted in claim 3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identificatof the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined Inventions I, II or III as well as to elect one species from the groups a-e as noted in the above paragraph even though the requirement be traversed (37 CFR 1.143).
- Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is** (703) 308-2034 and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL (703) 308-2034 Art Unit <u>1651</u> April 25, 2003

> Dr. Herbert J. Lilling Primary Examiner

Group 1600 Art Unit 1651